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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: FLOLAN

FDA Docket No. 95E-0418

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,338,325, which issued July 6, 1982. The application was filed on November 16, 1995, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

The applicant for patent term extension has also filed an application for patent term extension of U.S. Patent No. 4,883,812, which also claims the product "FLOLAN." However, since only one patent may receive an extension based upon the regulatory review period of "FLOLAN," the determination of the regulatory review period should refer to both U.S. Patent Nos. 4,338,325 and 4,883,812.

A handwritten signature in cursive script, reading "H. Bernstein".

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

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cc: David J. Levy, Ph.D.
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